



EUROPEAN COMMISSION

Brussels, 15.2.2012
C(2012)1103 final

COMMISSION IMPLEMENTING DECISION

of 15.2.2012

**concerning the transfer of the designation of "Pseudomonas exotoxin (domains II/III)-
Interleukin 13 chimeric protein" as an orphan medicinal product under Regulation
(EC) No 141/2000 of the European Parliament and of the Council**

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products¹, and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted on 13 December 2011 by PPD Global Ltd under Article 5(11) of Regulation (EC) No 141/2000,

Having regard to the opinion of the European Medicines Agency,

Whereas:

- (1) By Decision C(2002)1832 of 30 April 2002 the medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" was designated as an orphan medicinal product and entered in the Community Register of Orphan Medicinal Products pursuant to Article 5(9) of Regulation (EC) No 141/2000.
- (2) A change of designation holder is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already designated as an orphan medicinal product.
- (3) The application should therefore be granted,

¹ OJ L 18, 22.1.2000, p.1.

HAS ADOPTED THIS DECISION:

Article 1

The designation of the medicinal product "Pseudomonas exotoxin (domains II/III)-Interleukin 13 chimeric protein" as an orphan medicinal product, entered in the Community Register of Orphan Medicinal Products under number EU/3/02/101 and held by PPD Global Ltd, is transferred to EUDRAC Limited.

Article 2

This Decision is addressed to:

1. EUDRAC Limited, Hampden House, Monument Business Park, Chalgrove OX44 7RW, United Kingdom
- and
2. PPD Global Ltd, Granta Park, Great Abington, Cambridge, Cambridgeshire CB21 6GQ, United Kingdom.

Done at Brussels, on 15.2.2012.

For the Commission
Paola TESTORI COGGI
Director-General